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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,514	07/30/2003	Bret R. Shoberg	P-11234.00	7898
27581	7590	07/19/2006		EXAMINER
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			KAHELIN, MICHAEL WILLIAM	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,514	SHOBERG ET AL.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 May 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-56 is/are pending in the application.
 4a) Of the above claim(s) 44-56 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-43 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 30 July 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20050211;20040629</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input checked="" type="checkbox"/> Other: <u>IDS: 20030902;20030730</u> . |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 7/30/2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because a reference is less than two years before the filing date of the application and lacking a publication month. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Election/Restrictions

2. Applicant's election with traverse of claims 1-43 in the reply filed on 5/11/2006 is acknowledged. The traversal is on the ground(s) that examination of all claims poses no undue burden on the Examiner. This is not found persuasive because of the separate status in the art the two inventions have acquired, in view of their different classifications, thus requiring additional search.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 44-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/11/2006.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 5, 6, 9-11, 18, 20-27, 30, 31, 32, 39 and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al. (US 5,871,530, hereinafter "Williams").

6. In regards to claim 1, Williams discloses an elastomeric multi-lumen tube including a lumen with an inner surface forming a substantially elliptical cross-section (Fig. 5). The cross section includes a minor axis (extending radially outward from center) that is deformable such that the first length extends to a greater second length. Lastly, Williams includes an elongated conductor with a circular cross-section (18). The lumen of Williams is "substantially elliptical", insofar as the lumen of Applicant's Figure 3 is "substantially elliptical" and Williams' minor axis is inherently deformable to a greater second length due to the pliable nature of the constituent elastomeric material.

7. In regards to claim 2, Williams' conductor has an outer diameter "approximately equal" to the minor axis because there is only a small gap between the conductor and inner wall.
8. In regards to claims 6 and 27, the conductor is in the form of a coil (Fig. 5).
9. In regards to claim 9 and 30, the conductor is in the form of a cable (col. 7, line 39).
10. In regards to claims 10 and 31, the lumen includes a major axis (through lumen, tangential to the outer diameter of the lead) dividing the cross-section into asymmetrical sections (Fig. 5).
11. In regards to claims 11 and 32, the inner surface comprises a flattened portion (Fig. 5).
12. In regards to claims 18 and 39, the lead further comprises an overlay sheath (30).
13. In regards to claims 20, 21, 41 and 42, the lead may comprise silicone or polyurethane (col. 18, line 59).
14. In regards to claims 22 and 43, the proximal region of the lead may be made of silicone (col. 6, line 50), while the distal region is made of polyurethane (col. 18, line 59).
15. In regards to claim 23, the intersection of the conductor and the lumen forms two separate spaces having substantially crescent-shaped cross-sections (Fig. 5, small gap near the center of the lead body and much larger gap radially distal from the first gap).

16. In regards to claims 5 and 24-26, the conductor comprises a sheath of fluoro-polymer (col. 9, line 1; because the coating is an "enveloping structure", Examiner is interpreting it as a sheath), which makes it lubricious.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Williams. Williams discloses that the conductor comprises a sheath of fluoro-polymer (col. 9, line 1; because the coating is an "enveloping structure", Examiner is interpreting it as a sheath), and which has a minor axis/diameter equal to the lumen. Alternatively, it is well known to coat or sheath

conductors with fluoro-polymers, such as PTFE to provide an insulated, lubricous, and biocompatible coating for conductors. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Williams' conductor with a fluoro-polymer coating to provide an insulated, lubricous, and biocompatible coating for the conductor.

20. Claims 7, 8, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams. Williams discloses the essential features of the claimed invention except for an extendable and retractable electrode wherein a connector pin contact rotates a coil to extend and retract an electrode, and an elongated conductor in the lumen of the coil. It is well known in the art to provide extendable and retractable electrodes wherein a connector pin contact rotates a coil to extend and retract the electrode to provide a deployable active fixation mechanism that provides rigid fixation and avoids snagging during insertion, and elongated conductors in the lumen of coils to provide multipolar leads which can stimulate different areas of the heart with different voltages.

21. Claims 12-17, 19, 33-38 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Shoberg et al. (US 5,584,873, hereinafter "Shoberg"). Williams discloses the essential features of the claimed invention including a plurality of lumens offset from the center point of the tube (Fig. 5), a plurality of lumens comprising three lumens (Fig. 5), each of the plurality of lumens includes a circular cross-section (see US 5,303,704, col. 3, line 24, incorporated by reference), and a conductor extends within at least one of the lumens (Fig. 5). Williams does not

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expressly disclose a minimum wall thickness between approximately 0.002 inch and approximately 0.008 inch or an electrode with an outer diameter approximately equal to an overlay sheath. Shoberg teaches of providing a multi-lumen lead with a minimum wall thickness of approximately 0.008 inch (col. 4, line 9) to provide a lead that is both small to allow passage through small vessels and insulated enough to avoid short circuits; and an electrode (14) with an outer diameter approximately equal to an overlay sheath (12) to provide an isodiametric lead that will avoid snagging. Alternatively, it is well known in the art to minimize the diameter of leads to allow passage through small vessels and minimize trauma. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Williams' invention with a minimum wall thickness of approximately 0.008 inch to provide a lead that is both small to allow passage through small vessels and insulated enough to avoid short circuits; and an electrode with an outer diameter approximately equal to an overlay sheath to provide an isodiametric lead that will avoid snagging.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Williams et al. (US 5,246,014) is one of many teachings of a rotatable coil for extending an electrode.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

6/30/06

GEORGE R. EVANISKO
PRIMARY EXAMINER

1/31/